

Application No.: 09/745,751
Amendment Rule 111 dated September 29, 2005
Reply to Office Action dated June 29, 2005
Attorney Docket No.: 3486-018

EXHIBIT K

Wayne P. WILLIAMS, BDS, MchD



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/745,751 Confirmation No.: 1104
Applicant : HOCHMAN, Mark N.
Filed : December 21, 2000
TC/A.U. : 3763
Examiner : HAYES, Michael J.

Docket No. : 3486-018
Customer No. : 22440

DECLARATION UNDER 37CFR 1.132

I, Wayne P Williams, ^{BDS, MChD}
~~DDS~~ (← appropriate

degree), hereby make the following declaration in support of the above-named application:

1. I reside at 25 Priest Avenue, Wokingham,
Berkshire, RG40 2LT

2. I am a licensed dentist and I have been practicing Dentistry for 20 years.

3. I have written and published many articles in the field of dentistry, including articles related to ^{LOCAL} ANAESTHESIA. I have also reviewed many articles in this field and I am frequent lecturer, having made presentations all over the world.

4. A copy of current Curriculum Vitae is attached providing more details of my background and expertise in the field of dentistry.

5. One problem in the field of dentistry and more particularly, during the injection of an anesthetic into a living tissue prior to performing dental procedures pertains to needle bending. As a needle is introduced through tissues to a preselected site for delivering an anesthetic, it frequently bends. This action causes discomfort in the patient and pain. In many instances, a patient either stiffens up, or, worse, tries to move involuntary away from the needle, or close his mouth, thereby causing even more discomfort.

6. Recently, Dr. Mark Hochman disclosed to me his invention, that solves the problem of needle bending. More specifically, Dr. Hochman has disclosed to me:

a method of injecting a drug into a patient through a needle having a lumen comprising the steps of:

advancing said needle into the tissue linearly along a longitudinal axis of the needle;

simultaneously rotating the needle along its longitudinal axis to reduce deflection of the needle; and

injecting the drug.

7. Initially, I had some doubts that this procedure would work. However, I have tried this technique at least 500 times on patients and I found that it is very effective in reducing needle bending and, subsequently, in reducing or eliminating patient discomfort and pain.

8. I found that for the procedure was effective as long as I kept the needle rotating to change the orientation of the bevel of the needle in somewhat continuous manner during the insertion, and that the total angle of rotation of the needle, or whether it was rotated only in a single direction, or back and forth, did not matter that much. I found that it was very easy for me to determine intuitively how much to rotate the needle from the reaction of the patient. More particularly, if I did not rotate the needle enough to prevent it from bending, the patient became uncomfortable as indicated by his body language and other indicia, including verbal communication from the patient, Because of this immediate voluntary or involuntary feedback from the patient, it was very easy to adjust the procedure to each patient as required.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

 W.P. Williams

Dr.

Date:

09/09/2005

Summarised Curriculum Vitae

Wayne Phillip Williams

PERSONAL INFORMATION:

Date of birth 1964-05-06
Residential address 25 Priest Avenue, Wokingham, Berkshire, UK
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 wayne@smile2o.com (office)

TERTIARY EDUCATION / QUALIFICATIONS

1996 - 1999 MChD (Prosthodontics) *cum laude*, University of Pretoria, South Africa
1982 - 1987 BDS, University of the Witwatersrand, South Africa

Awards:

1998 Colgate Prize (IADR): post-graduate research (endodontics)
1982-1987 Metboard scholarship: academic achievement
1983-1985 University of the Witwatersrand scholarship: academic achievement
1986 Siemens Award: Albert Ludwig Institute, Freiberg, West Germany

CURRENT POSITION

- Founder - International academy for dental anaesthesia (IADA), London
- Specialist prosthodontist, d100, London
- Principal specialist, smile₂o, Wokingham (UK)

Registered specialist (Prosthodontist):

- Health Professions Council (South Africa) (DP 0047813)
- General Dental Council (United Kingdom) (67720)

PRIVATE PRACTICE

2004 - date	Principal and specialist prosthodontist, smile2o , Berkshire, UK
2003 - 2005	Specialist prosthodontist and lead clinician, Q Clinic, London, UK
2003 - 2005	Specialist prosthodontist, Harley Street Dental Clinic, London, UK
2001 - date	Specialist prosthodontist – d100, London, UK
2000 - 2001	Specialist prosthodontist - Menlo Park, Pretoria, South Africa
1990 - 1996	Senior partner - Welthagen, Prinsloo, Badenhorst and Williams

MEMBERSHIP OF PROFESSIONAL ASSOCIATIONS

2003 to date	LD Pankey Association (UK)
2003 to date	Council of Healthcare Advisors (USA)
2002 to date	Society for the Advancement of Anesthesia in Dentistry (SAAD), (UK)
2002 to date	Dental Sedation Teachers Group (DSTG), (UK)
2002 to date	Association of Dental Implantology (ADI)
2001 to date	British Dental Association (UK)
1999 to date	Academy of Osseointegration (AOO)
1992 to 2002	International Association for Dental Research (IADR) (International and South African Division)
2000 to 2002	International College of Prosthodontists (ICP)
1999 to 2001	IADR – Dental Materials Group (South Africa)
1996 to 2001	Academy of Prosthodontics (APSA), (SA)
1986 to 2001	South African Dental Association (SADA), (SA)

LECTURES/COURSES/WORKSHOPS presented at SCIENTIFIC MEETINGS

2005

- University of Basel (Switzerland)
- University of Berne (Switzerland)
- University of Zurich (Switzerland)
- Independent Seminars, Royal College of Physicians, London (UK)
Hands-on course in local anaesthesia (by invitation of Prof SF Malamed)
- Stoke-Mandeville Hospital (Oxford PGDE)

Hands-on course for safe and effective local anaesthetic delivery

- IADA hands-on course, Wokingham, UK

You can do miracles with local anaesthesia

- British Association of Dental Therapists, 42nd Annual Scientific Meeting, Arundel, UK

Safe and effective delivery of local anaesthesia

2004

- Updates in Prevention and Parodontal Therapy, University of Zurich, Switzerland
 - *Local anaesthesia in modern dental practice*
- 1st Members National Forum - Association of Dental Implantology, London, UK
 - *Screw- versus Cement-retained prosthetic design in implantology*
- Faculty of Dental Surgery, Royal College of Surgeons, UK
 - Implant Masterclass: *Implant management of the edentulous mandible*
- Continuing Professional Development (Dentsply, UK), Watford, UK
 - *Pain management of the acutely inflamed tooth*
- University Lecture Program (Switzerland)
 - University of Basel
 - University of Berne
 - University of Zurich
 - *New perspectives of local anaesthesia – a scientific approach*
- American Woman's Club of Zurich, Switzerland
 - *Local anaesthesia for oral hygienists- a practical overview*
- Addenbrooke's Postgraduate Medical Centre (BDA), Cambridge
 - *A new perspective on local anaesthesia*
- Dentsply Lecture Series, South Lodge, UK
 - *Can you do miracles with local anaesthesia?*
- Nobel-Biocare series, Q-clinic, London, UK
 - *Easy abutment for dental implants (hands-on course)*
- Eastman Dental Institute, Univ. College London
 - *Hands-on course: Inferior Alveolar nerve block techniques*

- IADA hands-on course, Wokingham, UK
 - *You can do miracles with local anaesthesia*
- Bishop's Stortford Study Group, Bishops Stortford, UK
 - *Occlusion: The confusion, illusion and conclusion*
- Luton and Dunstable Study Group, Luton, UK
 - *You can do miracles with local anaesthesia*
- London Dental Showcase, Excel, UK
 - *Local anaesthesia in modern dental practice*

2003

- Royal College of Surgeons, London, UK
 - *A colour revolution: Digital photography "seeing is believing"*
- 10th International Dental Congress on Modern Pain Control
 - *Crestal intraosseous approach (CIA). Introducing a novel injection. 4-year clinical report*
- Department of Postgraduate Medicine and Dentistry, University of Manchester, UK
 - *A numbing experience*
- The Pankey Association (UK), Oxford, UK
 - *Understanding success in local anaesthesia*
- American Dental Society of London, London, UK
 - *Mayhem, miracles or magic with local anaesthesia*
- Oxford Postgraduate Medicine and Dentistry, Reading Division, UK
 - *Occlusion: illusion, confusion and the conclusion*
- Oxford Division BDA CDS Group, Divisional Study Day, Vale of Aylesbury, UK
 - *Recent innovations in the delivery of local anaesthesia*
- Berkshire Restorative Study Group, Newbury, UK
 - *Understanding local anaesthesia*
- London Dental Study Club (LDSC), Saville Club, London, UK
 - *Immediate loading of endosseous dental implants*
- WAND-introductory lecture series (Switzerland)

Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry

- Zurich
 - Horgen
 - Langenthal
 - Saxer Institute for oral hygiene
 - Bern University
 - Q-academy, London
 - *Safe and effective local anaesthesia in dentistry- a hands-on course*
 - 1st Practice Works user conference (UK), Birmingham, UK
 - *Digital Dentistry – clinical applications and profitability*
 - Post-graduate course for Oral Hygienists, Hove, UK
 - *Local anaesthesia for oral hygienists*
 - Guildford Section Meeting (BDA), Guildford, Surrey
 - *An insight into safe and effective local anaesthesia*
 - Advances in surgical and prosthetic implantology - Southern Implants, London, UK
 - *Dental implants - immediate, immaculate, immortal or impossible*
 - *Why wait? – a rationale for implant management of the growing patient*
 - Swiss Association of Oral Implantology, Zurich, Switzerland
- New perspectives on local anaesthesia*

- Dentsply post-graduate lecture series
 - South Lodge, UK
 - Claudius Ash, UK
- IADA hands-on course, Cheltenham, UK

Making the WAND work for you

- IADA hands-on course, Apsley, Hemel Hempstead, UK

Miracles with local anaesthesia

- BDHA (SE regional group) Brighton, UK

Understanding safe and effective local anaesthesia

- IADA hands-on course, Twickenham, UK

- *Safe and effective delivery of local anaesthesia*

2002

- 8th International Congress, Turkish Endodontic Society, Istanbul, Turkey
 - *Endodontic anaesthesia*
- 7th Private Prosthodontic Group meeting, Algarves, Portugal
 - *Implants in the growing/ adolescent patient*
- 1st International Dental Congress of the Selcuk University, Konya, Turkey
 - *Growth Potential Protocol and the use of implants in growing patients*
 - *Creating a new perspective on the use of local anaesthesia in dental practice*
- Department of Postgraduate Medicine and Dentistry, University of Manchester, UK
 - *A numbing experience*
- Royal College of Surgeons, London
 - *A colour revolution: Digital photography "seeing is believing"*
- Dentsply Pharmaceuticals, Northwood, London
 - *Can you feel it? An update on local anaesthesia*
- 1st WAND-users meeting (UK), Hertfordshire, UK
 - *Does the WAND really work?*
- BDA Southampton Section meeting
 - *A new perspective on local anaesthesia*
- 4th Bio-osseous materials meeting – FM Dental, Krakow, Poland
 - *Integrating materials with knowledge, technology and skill*
- Gloucester independent study group, Ashchurch, Gloucester
 - *Can we do miracles with local anaesthesia?*
- Guildford Dental Vocational Scheme meeting, Guildford, UK
 - *Understanding local anaesthesia*
- Harley Technicians Study Club, London, UK
 - *Communicating without speaking.....?*
- Gloucester Independent Dentists (GID) study day, Gloucester, UK
 - *Understanding local anaesthesia*

2001

- 7th Scientific Congress Polish Stomatology Society, Lodz, Poland
 - *New techniques for local anaesthesia in dentistry*
- 38th Odontologic Congress (Swedental 2001), Stockholm, Sweden
 - *New techniques for local anaesthesia in dentistry*
- 4th Unident Scientific Meeting, Falkenberg, Sweden
 - *An update on local anaesthetic techniques in modern dentistry*
- 8th International Dental Congress, Turkish Dental Association, Istanbul, Turkey
 - *Computer-controlled intraligamentary anesthetic delivery. A new perspective on local anesthesia in dentistry*
- 2nd Scientific Meeting – Images of Modern Dentistry, Wokingham, Berkshire, UK
 - *Endosseous oral implantology in the growing /adolescent patient*
 - *Occlusion: The Confusion, Illusion and Conclusion*
 - 2nd Milestone International Distributor Training Congress, Lonehill, South Africa
 - Course co-ordinator and principal lecturer
 - Italy lecture series (December)

Understanding local anaesthesia in dentistry

- Padova
- Torino
- Pescara
- Piacenza
- Netherlands (key opinion leaders study group):
 - Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry*
 - Nijmegen
 - Norway lectures series (February):
 - Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry*
 - Oslo
 - Bergen

- Denmark lecture series (February)
 - Copenhagen
 - Arhus
 - Dental Expo Africa 2001 (workshops)
 - *Computer-controlled intraligamentary anaesthetic delivery*
 - 1st SA Military Health Service Oral Health Congress
A new perspective on the use of local anaesthesia in modern dental practice
- 2000
- 9th International Dental Congress on Modern Pain Control “A New Millenium in Analgesia, Sedation and Anaesthesia, Jerusalem, Israel
 - *Intra-ligamentary anaesthetic delivery: Avoiding complications*
 - *The latest developments in computer-controlled local anaesthetic delivery*
 - 11th Saudi International Dental Meeting - Saudi Dental Society, Riyadh, Saudi Arabia
The WAND: a computer-controlled local anaesthetic delivery system
 - 10th Central European Dental Exhibition, Łódź, Poland
Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry
 - 34th Scientific Meeting of the IADR, Stellenbosch, South Africa
Endosseous oral implants in adolescent patients – growth potential protocol (GPP): A case report
 - Swedental 2000, Stockholm, Sweden – Swedish Dental Association and Swedish Dental Trade Association
Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry
 - 2nd Konferencja Osteologia W Krakowie 2000 (Williams, Nevins, Haegewald)
 - *Implants in adolescent patients - the growth potential protocol*
 - *The WAND: a computer-controlled local anesthetic delivery system*
 - Poland Lecture Series (November 2000):
Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry
 - Krakow (Instytut Stomatologii CM, University Jagellonicae)

- Warsaw
- Poznan
- Krosno
- Lódz (Medical University of Lódz)
- 2nd Southern Implants (Greece) Meeting, Glyfada, Athens, Greece
 - *Implants in adolescent patients - the growth potential protocol*
 - *The WAND: a computer-controlled local anesthetic delivery system*
- Faculty of Health Services (Dental and Paramedical Sciences), Technikon Pretoria
Dental Assistants Course, Warmbaths, South Africa
 - *The important role of the dental assistant in the use of the WAND*
- Anglo-Saxon Dental Study Group, Jerusalem, Israel
 - *Aesthetic Dentistry in the Year 2000 - "a view from a different angle"*
- UK Lecture Series (June 2000):
 - *Computer-controlled local anaesthetic delivery – a new perspective on local anaesthesia in dentistry*
 - Glasgow
 - Manchester (Mandec, Manchester Dental School)
 - *Royal College of Physicians, London*
 - *Edgbaston, Birmingham*
 - *International Centre for Excellence in Dentistry (ICED) & Eastman Dental Hospital*
 - *University of Wales, College of Medicine, Dental School*
- 1st Scientific Meeting – Images of Modern Dentistry, Harrow, Middlesex, UK
 - *Rationale of successful endodontics: a practical guide*
 - *Local anaesthesia in dentistry – a new perspective*
- Dentsply / Maillefer Training course (Irene Country Lodge, South Africa)
 - *Advanced endodontics – hands on course*
- 1st Milestone International Distributor Training Congress, Sandton, South Africa
 - Course co-ordinator and principal lecturer

- Dentistry 2000 - British Dental Association and British Dental Trade Association (NEC Birmingham, UK)

The WAND: A computer-controlled local anesthetic delivery system

- Pinner Study Group, London

The importance of effective communication between dentist & technician for the ultimate aesthetic result

- London Dental Showcase 2000, Olympia, London

The WAND: A computer-controlled local anesthetic delivery system

- Normandy Study Group, Rouens, France

A new perspective on local anaesthesia

- Pietermaritzburg Study Group, South Africa

Electronic local anaesthetic delivery systems

- Gauteng Oral Health Services – CPD 2000

A new perspective on local anaesthesia

1999

- 77th General Session of the IADR, Vancouver, Canada (Hatton Award Presentation)

Antimicrobial Effectiveness of Electro-chemically-activated water as an endodontic irrigation solution

- New York University (Ashman Institute for Implantology) (NY, USA),

Endosseous oral implants and the growing patient

- Tel Aviv University (Israel)

Computer-controlled local anaesthesia in dentistry

- Haddasah University (Israel)

Computer-controlled local anaesthesia in dentistry

- Namibian Dental Association (Swakopmund, Namibia),

Annual General Meeting/ Conference

A new perspective on local anaesthesia in dentistry

- 1st Masterclass in Restorative Dentistry, Pretoria, South Africa

Occlusion: Illusion, Confusion, and the Conclusion

- 1st Skills Transfer Symposium, IADR (SA Division), Glenburn Lodge, South Africa

A new perspective on local anaesthesia in dentistry

- University of Pretoria, Annual Refresher Course, Pretoria
A Revolution in dental anaesthesia
- 33rd Scientific Meeting of the IADR (SA Division), Glenburn Lodge, South Africa
Amelogenesis Imperfecta: A case report
- Academy of Prosthodontics (SA), Underberg, Kwazulu-Natal
A protocol for treating growing patients with endosseous oral implants:
Case presentations
- East-Rand Study Group, Boksburg
Using electronic local anaesthetic delivery systems
- NOMADS, 1st Annual General Meeting, Wanderers, Johannesburg
Advanced electronic systems for local anaesthetic delivery
- White River Congress (SADA), Greenway Woods, South Africa
Modern endodontic techniques
- University of Pretoria – Continuing Education Course
Modern instrumentation for good endodontics

1998

- 32nd Scientific Meeting of the IADR, Worcester, South Africa
Antimicrobial Effectiveness of Electro-chemically-activated Water as an
Endodontic Irrigation Solution
- Clinical Consultant - Milestone Scientific Inc. (1998, 1999)
Presentations at various (regional/ national) meetings throughout South Africa

1997

- 31st Scientific Meeting of the IADR, Cape Town, South Africa
PL Kemp, CH Driessen, WP Williams* Reinforcement of a Denture-base Polymer
with a Composite Carbon and Glass Fibre Strengthen. *Journal Of Dental Research*,
77 (# 68), IADR Cape Town